IN THE CLAIMS:

1. An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric release region that controls the release of said therapeutic agent upon administration to a patient, said polymeric release region comprising a silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units.

2. The implantable or insertable medical device of claim 1, wherein said polymeric release region is a carrier region that comprises said therapeutic agent.

3. The implantable or insertable medical device of claim 1, wherein said polymeric release region is a barrier region disposed over a therapeutic-agent-containing region that comprises said therapeutic agent.

4. The implantable or insertable medical device of claim 1, wherein said polymeric release region is in the form of a coating layer that covers all or a part of said medical device.

5. The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is selected from a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch and a shunt.

6. The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is adapted for implantation or insertion into the coronary vasculature, peripheral vascular system, esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.

7. The implantable or insertable medical device of claim 1, wherein said therapeutic agent is selected from one or more of the group consisting of anti-thrombotic agents, anti-proliferative agents, anti-inflammatory agents, anti-migratory agents, agents affecting extracellular matrix production and organization, antineoplastic agents, anti-

mitotic agents, anesthetic agents, anti-coagulants, vascular cell growth promoters, vascular cell growth inhibitors, cholesterol-lowering agents, vasodilating agents, and agents that interfere with endogenous vasoactive mechanisms.

8. The implantable or insertable medical device of claim 1, wherein said silicone copolymer has an elogation at break of at least 25% at ambient temperature.

9. The implantable or insertable medical device of claim 1, wherein said non-siloxane units are elevated T_g non-siloxane units corresponding to monomers selected from vinyl monomers, aromatic monomers, methacrylic monomers, acrylic monomers and alkene monomers.

10. The implantable or insertable medical device of claim 1, wherein said copolymer is a block copolymer comprising (a) a block of said siloxane units and (b) a block of elevated T_g non-siloxane units.

11. The implantable or insertable medical device of claim 10, wherein said block of said elevated T_g non-siloxane units is selected from poly(vinyl monomer) blocks, poly(aromatic monomer) blocks, poly(methacrylic monomer) blocks, poly(acrylic monomer) blocks and poly(alkene monomer) blocks.

12. The implantable or insertable medical device of claim 10, wherein said block of said elevated T_g non-siloxane units is selected from substituted and unsubstituted polystyrene blocks.

13. The implantable or insertable medical device of claim 10, wherein said block of said elevated T_g non-siloxane units is selected from substituted and unsubstituted poly(alkyl methacrylate) blocks.

14. The implantable or insertable medical device of claim 10, wherein said block of said elevated T_g non-siloxane units is selected from poly(styrene) blocks, poly(methyl methacrylate) blocks, poly(ethyl methacrylate) blocks, poly(isopropyl methacrylate)

blocks, poly(isobutyl methacrylate) blocks, poly(t-butyl methacrylate) blocks and poly(cyclohexyl methacrylate) blocks.

15. The implantable or insertable medical device of claim 10, wherein said block copolymer comprises (a) a first glass transition temperature that is greater than ambient temperature and (b) a second glass transition temperature that is less than ambient temperature.

16. The implantable or insertable medical device of claim 15, wherein said first glass transition temperature that is greater than 75 °C and said second glass transition temperature that is less than 0°C.

17. The implantable or insertable medical device of claim 1, wherein said non-siloxane units are low T_g non-siloxane units corresponding to monomers selected from acrylic monomers, methacrylic monomers, vinyl ether monomers, cyclic ether monomers, ester monomers, unsaturated hydrocarbon monomers, and halogenated unsaturated hydrocarbon monomers.

18. The implantable or insertable medical device of claim 1, wherein said polymeric release region further comprises a supplemental polymer.

19. The implantable or insertable medical device of claim 10, wherein said block copolymer comprises at least two different types of said elevated T_g non-siloxane units.

20. The implantable or insertable medical device of claim 1, wherein said medical device is sterilized using a quantity of radiation effective to kill pathogens.

21. The implantable or insertable medical device of claim 1, wherein said silicone copolymer comprises first and second glass transition temperatures, and wherein said first glass transition temperature is below ambient temperature and wherein said second glass transition temperature is above ambient temperature.

22. The implantable or insertable medical device of claim 10, wherein said block of said siloxane units corresponds to a rubbery phase within said release region at ambient temperatures, and wherein said block of said elevated T_g non-siloxane units corresponds to a hard phase within said release layer at ambient temperatures.

23. The implantable or insertable medical device of claim 10, wherein said block copolymer is selected from a diblock copolymer, a triblock copolymer and a graft copolymer.

24. A method of forming the implantable or insertable medical device of claim 1, comprising: (a) providing a solution comprising (i) a solvent system and (ii) said silicone copolymer; and (b) forming said release region from said solution by removing said solvent system from said solution.

25. The method of claim 24, wherein said solution further comprises a therapeutic agent in dissolved or dispersed form.

26. The method of claim 24, wherein said solution is applied over a therapeutic-agent-containing region that comprises said therapeutic agent.

27. The method of claim 24, wherein said release region is formed by a technique comprising a spraying process.